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23483	7590	03/04/2010	EXAMINER	
WILMERHALE/BOSTON			VU, JAKE MINH	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/532,618	Applicant(s) TAMARKIN ET AL.	
	Examiner Jake M. Vu	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-19,21-32,34,35,37,47,50,57,60,62-78,80,83,85 and 87 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/11/09,11/02/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-6,8-15,17,18,25,26,28,37,47,57,62,63,66-78,80,83,85 and 87.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 12/14/2009; and Information Disclosure Statements filed on 11/11/2009 and 11/02/2009.

- Claims 16, 26, 28, 37 have been amended.
- Claims 1-6, 8-19, 21-32, 34-35, 37, 47, 50, 57, 60, 62-78, 80, 83, 85, 87 are pending in the instant application.
- Claims 1-6, 8-15, 17-18, 25-26, 28, 37, 47, 57, 62-63, 66-78, 80, 83, 85, 87 have been previously withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to the lowest percentages of the five ingredients equal 100.3%, **is withdrawn** in view of the amendment to independent claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over ABRAM (US 6,730,288, in which PCT pub date is 03/23/2000) in view of REED et al (US 6,299,900) and SHAHINPOOR et al (US 2002/0182162) **are maintained** for reasons of record in the previous office action filed on 09/14/2009 and as discussed below.

Applicant argues that each and every one of the suitable occlusive agents listed in Abram is a solid, with the exception of mineral oils (which can be solid or liquid). Abram states that "[i]n a preferred embodiment the occlusive agent is petrolatum" (Abram at col. 2, lines 45-56, emphasis added). All of Abram's examples contain petrolatum (see Table 1 in col. 4). Abram's example 2 demonstrates that the more petrolatum that is included in the composition, the more effective the composition becomes ("[i]ncreasing concentrations of petrolatum in topical mousse formulations containing 0.05% clobetasol was able to increase the in-vitro human epidermal penetration of the steroid in both intact and stripped skin models" (col. 6, lines 2-5)). So it is clear that petroleum is not merely a preferred component it is an essential component. Thus, Abram teaches the use of solid occlusive agents and not liquid hydrophobic solvents. While liquid hydrophobic solvent can be used as a co-solvent (e.g., alkyl benzoate or caprylic/capric triglycerides), they necessarily occur in the presence of a substantial amount of petrolatum. By advocating the use of skin occluding agents, in fact, Abram teaches away from the instant invention. Thus one of ordinary skill in the art, after reading Abram, would be especially motivated to select petrolatum-

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based compositions to form an occlusive barrier layer and to deliver an active agent and would be taught away from compositions lacking high levels of petrolatum. In contrast, the instant claims specifically exclude petrolatum, noting the disadvantages of such occlusive layers, in particular, petrolatum-containing layers. The Examiner finds this argument unpersuasive, because ABRAM teaches using other occlusive agents, such as mineral oil, and is not limited by the examples. (If this was the case, then Applicant's claims should be limited by the examples). Thus, it would have been obvious to one skilled in the art to use petroleum or mineral oil.

Applicant argues that the Office Action also asserts that Abram discloses the use of polymeric gelling agents, based upon a passing reference to conventional pharmaceutical adjuvants such as "viscosity modifying agents." There is no teaching of polymeric gelling agents as recited in claim 16. The Office Action assertion that "viscosity modifying agents" reads on "water gelling agents", much less "about 0.1% to 5% by weight of composition [of a] water gelling agent," is not well taken. Viscosity modifying agents encompass a range of materials and functionalities. For example, viscosity modifying agents could either increase or decrease viscosity or change the response of the composition to various rheological forces, such as shear. It is not clear from the teaching of Abram that water gelling agents are contemplated as 'viscosity modifying agent', if for no other reason that Abram does not state what desired effect his viscosity modifying agent is intended to achieve. Abram most certainly does not provide a specific disclosure to prepare foamable compositions using water gelling agents. Water gelling agents are used to stabilize the aqueous phase of the emulsion (see

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paragraph [0107]), which is not taught or suggested by Abram. Moreover, the specification clarifies another aspect of the relevance of the gelling agent as follows: The combination of a surface active agent, foaming adjuvant and water gelling agent according to one or more embodiments of the invention provides a low specific gravity foam having superior flow properties and sheer breakability (among other attributes). Paragraph [0120]. The Examiner finds this argument unpersuasive, because Applicant's specification disclosed that "the water gelling agent according to one or more embodiments of the present invention stabilizes the aqueous phase by, for example, increasing viscosity and linking capability (see [0107]). Thus, viscosity modifying agent would reasonable read on water gelling agent.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618